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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,009	04/05/1999	CLAIRE E. LEWIS	550-128	1771

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	21

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/284,009	Applicant(s) LEWIS ET AL	
	Examiner Celine X Qian	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *87-93,101,104,109-116 and 120-125*.

Claim(s) withdrawn from consideration: _____

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: it does not overcome the 112 1st paragraph rejection set forth of the record mailed on 3/13/03. In response to the rejection, Applicants argue that the Naylor Declaration provides sufficient support for the enablement of the claimed invention because the Declaration asserts that replacement of the marker gene taught by the specification with a therapeutic gene would have been considered routine experimentation for one of ordinary skill in the art. The examiner does not dispute this notion, however, Applicants are reminded that the non-enablement rejection is not based on how to make a vector comprising a therapeutic gene but on how to achieve high and sustained level of expression of the therapeutic gene in vivo, hence achieve a therapeutic effect. The technical difficulties of cell based gene therapy has been discussed in detail in the office actions mailed on 8/26/02 amd 3/11/03. Neither the specification, nor the Naylor Declaration provides sufficient teaching to overcome these difficulties. Applicants assert that the screening cells ex vivo for levels of expression is a matter of routine experimentation. However, such ex vivo screening does not ensure the high and sustained expression in vivo after cell administration (discussed in detail in previous office actions). Consequently, the claimed invention is not enabled.

Applicants also cited US patent 6,265,390, Nishihara et al (1997)., and Fluth et al (2001) to support the enablement of the claimed invention. US patent 6,265,390 does not support the enablement of the claimed invention because it also fails to teach how to achieve high and sustained level of expression of a therapeutic gene in vivo to achieve a therapeutic effect by delivering a mononuclear phagocyte. Nishihara et al. does not teach delivering a monoclear phagocyte comprising a therapeutic gene either. In addition, Nishihara et al. was published in 1997, and Fluth et al. was published in 2001. The priority date for the claimed invention is 10/9/1996. The claimed invention needs to be enabled at the time the invention was made. Therefore, Nishihara et al. and Fluth et al. cannot be relied on for supporting the enablement of the claimed invention. Therefore, the 112 first paragraph rejection is maintained.